Improvement of packaging equipment efficiency from pharmaceutical industry with Kaizen Lean methodologies

Kaizen Institute

Sofia Luísa Helfer Carvalho

Department of Engineering and Management, Instituto Superior Técnico

Abstract

Given the current economic climate and the increasing globalization of the economy, competition between companies has been growing. Therefore, it is essential to reduce costs, to improve the quality and the service level. For that, Kaizen Lean tools and methodologies are being applied and the main goals are to eliminate activities that do not add value to the customer and to establish a continuous improvement culture. Based on this context, Empresa X, which operates in the pharmaceutical industry, wants to improve by 30% the efficiency from three packing lines of solid medicines from its Portuguese factory, applying Kaizen Lean tools and methodologies. This company is a client from the Kaizen Institute (KI) consultant, with which this work was carried out.

Supported by examples from literature review, the present paper describes how Kaizen Lean methodologies and tools, namely Daily Kaizen, Single Minute Exchange of Die (SMED), Kobetsu Kaizen and Kamishibai, have been integrated and used to increase the efficiency of those lines.

The main result obtained, five months after the project start, was an efficiency increase of 27% from those three packing lines.

Keywords: Pharmacy, Lean, Kaizen, Muda, SMED (Single Minute Exchange of Die), Kobetsu Kaizen

1. Introduction

The global economy after the recent crisis, continues to recover, however this recovery is slow and uneven at the European level. European Eurozone countries are faced with the possibility of stagnation and low inflation (IMF 2015). Against this background, it is crucial that companies increase the quality of their products and services at a lower cost. Thus, companies operating in very competitive markets and rapid change have begun to implement the principles of Lean Thinking (LT) (Fullerton, Kennedy, & Widener, 2014).

Lean was the name given to the Japanese Production System originated in Toyota Motor Company, because it eliminates superfluous "fat" in business, in other words “muda” (Holweg, 2007).

According to Taiichi Ohno there are seven types of muda: Overproduction, inventory, defects, motion, processing, waiting and transport (Uitdehaag, 2011;Verrier, et al., 2013).

Gemba is the place where value is added. The main pillars of gemba kaizen are: muda elimination, 5S methodology and standardization. It is important to eliminate muda, maintain the workplace organized and clean, and standardize the best procedures (Imai, 2012).

Empresa X is a leading CDMO (Contract Development and Manufacturing Organisation) in the pharmaceutical industry. It is looking for a way to increase by 30% the efficiency of three packing lines of solid medicines in its Portuguese factory.

To achieve this, KL tools and methodologies have been implemented, in the packaging area, to reduce the setup time, reduce the minor stoppages and increase the machines speed.

These paper explains how the initial data was collected and analysed, and later, how KL methodologies and tools were integrated and implemented.

In the next section a brief literature review is done about Kaizen Lean. The section 3 presents the methodology used. In section 4 the case-study is introduced, where the two main processes from the Portuguese factory of Empresa X are described: The production process and the packaging process. In section 5, the planning phase, it is explained how the data was collected and analysed. In this section a set of improvement proposals is also presented. In section 6, the implementation phase is described. In section 7, the results obtained are discussed. Finally, in section 8, the main conclusions and the proposed future actions to improve the results are presented.

2. Literature Review

To achieve quality, less costs, better service and more motivation, it is necessary to maintain efficient operations in order to minimize waste and cultivate a mindset of continuous improvement. The integration of Lean Thinking principles allow not only to improve the performance of a company at a lower cost, but also prepare it for an eventual change.

Melton (2005) argues that the structured approach, present in Figure 1, should be used to Lean Thinking when the aim is to apply the principles of adding value, waste and work flow.

Figure 1: Methodology

The Lean Leadership is the link missing between Lean production methods and continues improvement processes. Dombrowski & Mielke (2013) presents in his case-study five fundamental principles to describe a Lean Leadership system: Improvement culture, the leader personal development, workers training, Gemba and implementation of Lean policies.

Since the early 2000s the Lean research in health has been the subject of research (Radnor et al., 2012). For example, the Denver Health and Hospital Authority estimated to have increased the value of sales at $ 58 million and decreased the value of their spending since it

first applied the KL tools for five years (Dart, 2011). The literature in this area of health focuses mainly in the application of Lean in hospital management rather than pharmaceutical management. So the packaging problem in this report is be seen as a production problem.

Based on published examples, the Kaizen Lean tools with the greatest impact on an efficiency increase project are presented below:

- **Single Minute Exchange of Die (SMED):** A case-study from (Mo, 2009) demonstrates how a company, producer of furniture, adapted SMED to reduce setup time from 45 minute to 15 minutes.

- **Kobetsu Kaizen:** Sütőová (2012) conducted a case study on the implementation of the Kobetsu Kaizen in a company that produces and sells packaging materials for the food industry, specifically in the printing presses. With this tool, the time lost with minor stoppages of the pressure rollers was reduced by 78% and that of the cooling drums by 84%.

3. Methodology

The methodology used to elaborate the study on hand, follows Melton's proposed structure to apply Lean Thinking, which is presented in Figure 1 (Melton, 2005).

First the current process is observed and the necessary data is collected in order to identify the value and non-value activities (1). Then these data are analysed with the gemba team to find the main causes of the problems detected (2). After the conclusion of the first two steps, improvement activities are designed with the same team, and a new paradigm is created (3). Finally, the new activities are implemented (4) and the results evaluated and discussed (5).

4. Case-Study

Empresa X is an important player in the pharmaceutical industry. It offers manufacturing services of pharmaceuticals in various dosage forms, production of clinical trial material and pharmaceutical product development. The Company operates fourteen manufacturing facilities and two development facilities around Europe. This study was developped in one manufacturing facility located in Portugal. In this facility are produced and packed tablets and capsules.

After the production process, the medicines are packege. This process is involves five machines, placed in line:

A. **Blistering:** The bulk, as the pharms are called by Empresa X, is introduced in alveolus from a polyvinyl chloride (PVC) tape. The drug can be introduced through three different feeding systems:

   - SYPRO - dynamic structure with several pipes that introduce the bulk directly into the alveoli;

   - Rail system - cabin in which the bulk slide by troughs and enters directly into the alveoli;

   - Universal supply system - cabin in which a generous amount of bulk is disposed on the PVC tape and the excess is removed by a brush.

   Afterwards, this tape is sealed with aluminum. On this final tape is subsequently recorded the batch and the validity with a mechanical stamp. At the end, the blisters are cut.

B. **Packing:** The blisters are grouped by a robot according to the number of blisters

each package takes. Then, the blisters and leaflets are placed into the packages.

C. **Balance:** It verifies if the correct number of blisters and the leaflet were introduced into the package.

D. **NERI:** To each package is added a label or a printed registration required by the customer. Whenever a package is detected unlabeled or off the record, this is rejected.

E. **Clustering:** The packages are grouped forming sets which are wrapped with polythene film. These sets are encased manually into cartons by the operator of the secondary room. These cartons are over a pallet. When this pallet is full, it is moved to the end of the secondary room with a pallet truck.

In this work we intend to improve the efficiency of the three packaging lines in order to increase the production capacity and productivity. Thus, the objective is to increase 30% the value of the Overall Equipment Effectiveness (OEE). OEE is an effective way to analyze the efficiency of a machine or set of machines, taking into account the most important and common cause of yield loss. The causes of yield loss are classified into three categories: Availability, performance and quality, which is excellent to understand the source of problems (Gupta & Garg, 2012; Ahire & Relkar, 2012). To support this goal it is necessary to reduce setup times, to reduce the main causes of stoppages and to increase the machines speed. These can be achieved with the help of Kaizen Lean tools and methodologies.

5. Planning phase

In this section are presented the first three steps of the Methodology, namely: Collection and analysis of data, and improvement activities proposal.

Thus, the first part explains the proceeded used to collect data. Then, the main Key Performance Index (KPI) of the ongoing work is presented, the Overall Equipment Effectiveness (OEE), and the way it is calculated. In the following part, the data collected is analysed. After explaining the collection and analysis of data, improvement activities are proposed.

5.1. Data Collection

The first step of this study was the observation of the current state of the packaging process in order to gather opportunities for improvement. For this, a Logbook to collect important data of the lines was created. At this point, Empresa X did not collect detailed data of the packaging process, namely, the length of the setup of the machines and the causes of production stoppages. With the Logbook was possible to collect the necessary data to calculate the OEE, identify the reasons for the stoppages and seeking opportunities for improvement.

A gemba walk took place (walk through the place where value is added), where a setup was also observed, with the various stakeholders of Empresa X to identify waste operations. During this walk the team observed different types of waste such as: Lack of standardization of the setup process; lack of a parts checklist for the setup; production of defective blisters, packages and sets; and consequently, reprocessing waste.

5.2. Data Analysis

After the data collection, comes the data analyse. The OEE corresponding to October and November of the three packaging line is presented in Figure 2. The OEE is obtained by

multiplying the amount in percentage of three categories: Availability, performance and quality (Equation 1) or by dividing the actual number of blisters with quality produced with the number of blisters that could have been produced (Equation 2) (Gupta & Garg, 2012; Ahire & Relkar, 2012).

$$\text{OEE} = \text{Disponibility} \times \text{Performance} \times \text{Quality} \quad (1)$$

$$\text{OEE} = \frac{\text{Actual number of blisters produced with quality}}{\text{Number of blisters that could have been produced}} \quad (2)$$

As it is possible to see in Figure 2, line C is the line with the lower OEE. This lack of efficiency is due to the fact that this line produces smaller batches than the average and therefore has more changes.

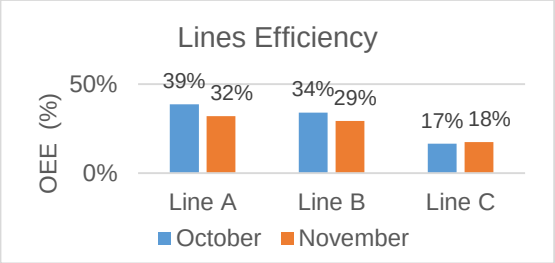

Figure 2: OEE from October and November per line

- **Availability Analysis**

Using the data collected with the Logbook during the months of October and November, it was possible to analyze the major losses that occurred in the three packaging lines. These loses can be seen in the Figure 3, which represents the total hours lost in the three lines.

As represented in the graph of Figure 3, the lines main stoppage cause are the “setups” with a loss of 519 hours. Second, with an impact of 189 hours, appears "Interval / meal". The lines stopped during meals and intervals.

Consequently, the lines took some time to turn on again. In third place, comes the "Bulk", representing a loss of 162.75 hours.

Bulk problems are due, among other things, broken or oversized tablets, crushed capsules and excessive dust. In fourth place is the cause of "Others", i.e. a set of problems that occur occasionally and thus are not easily controllable. The leaflets originate the fifth major stoppage cause, representing 111 hours. Problems that occur because of the leaflets are related to the lack of standardization of size of these and of the machines tuning parameters. The leaflets can be thicker or thinner other longer or shorter.

- **Performance Analysis**

During gemba walk it was observed that the three package lines were not always operating at the standard speed. As a result of low speeds, the yield of the entire line is lower, i.e., the line produces less than its potential. The yield of Line A, Line B and Line C are, respectively, 92%, 86% and 81%.

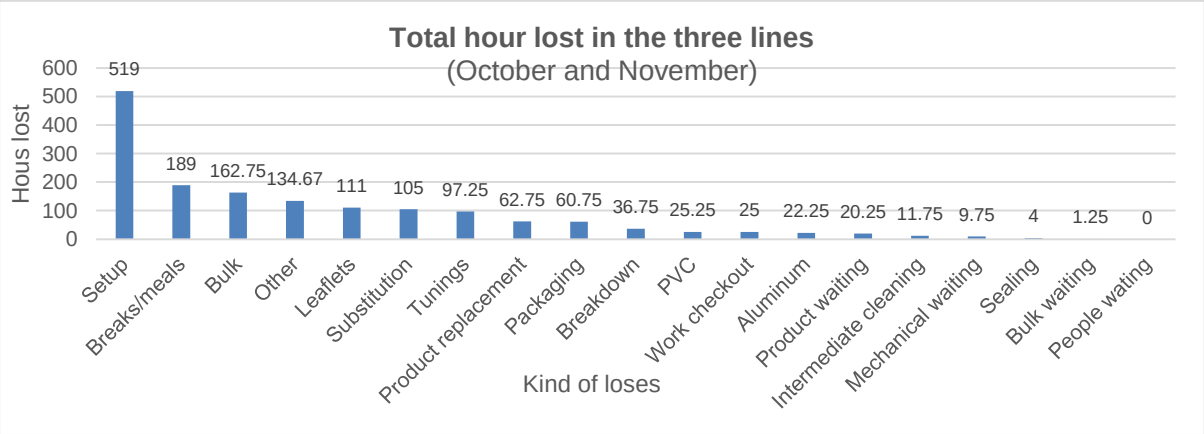

Figure 3: Total hours lost in the three lines

- **Quality Analysis**

In the drug packaging process the quality problems have two types of origin: consumable and intermediate products, such as damage leaflets and broken bulk; and secondly tuning parameters, which weren't standardize. The level of quality Line A, Line B and Line C are respectively 87%, 83% and 85%.

5.3. Improvement proposals

After analysing the data collected and based on opportunities found, the next step is to design a solution to the actual paradigms. The proposed solution meets the objectives initially defined and included the Kaizen Lean tools and methodologies that were selected during the Literature Review. This solution is divided in four stages:

- **Stage 0 - Basic Stability:** The implementation of the Daily Kaizen will create a normalized communication channel between workers and a culture of continuous improvement. Also in this stage a Mission Control Room is build, to follow and manage all these project.
- **Stage 1 - Setup reduction:** The Single Minute Exchange of Die (SMED) tool and the Value Stream Mapping (VSM) were applied to reduce the setup time and so increase the lines availability. There are three setups types (total, parcial or batch/order setup), however the main focus will be in the parcial setup because this is the one that occurs most of the time.
- **Stage 2 - Minor stoppage reduction:** The main kind of minor stoppages losses are bulk and leaflets. To reduce those incidences the Kobetsu Kaizen tool was applied.
- **Stage 3 - Speed increase:** In this stage was implemented a Kamishibai audit to guarantee that the lines are operating in the normalized speed.

6. Implementation Phase

The fourth step of the Methodology is the implementation of the improvement activities proposed.

Stage 0 deals with the basic stability necessary for the success of the work, which is guaranteed with the implementation of Kaizen Daily (KD) and the Mission Control Room (MCR). After, the Stage 1 describes the improvement in activity which aims to reduce the setup time. For this purpose, two tools KL were applied: Value Stream Mapping (VSM) and Single Minute Exchange of Die (SMED). Then, in Stage 2, two Kobetsus Kaizen (KK) were implemented, to reduce the minor stoppages related to the bulk and the leaflets. Finally the Stage 3, describes the application of the audit Kamishibai to ensure that the lines are operating to the standard speed.

6.1. Stage 0 - Basic Stability

In this stage KD was implemented to create a communication channel and to better manage the production and mechanical teams. This methodology facilitated the identification of new problems and discuss possible solutions to avoid them in the future. During these work seven standard were created to improve the process and eliminate variability. Also boards to establish communication between production and mechanical teams, and to guarantee a smooth production flow were created.

The main players of this project gathered together, once a week, in the MCR to discuss the results obtained with the improvement

activities. This meeting allowed the team not only to follow the evolution of the results but also to react if something new appeared. From these meetings, come out the idea to continue working during the lunch and break time, increasing so the lines efficiency.

6.2. Stage 1 - Setup reduction

The Stage 1 follows the SMED tool. According to Shingeo Shingo, internal tasks are those that can only occur during the setup; external tasks are those that can occur with the line in normal operation.

The SMED is divided in four main steps:

1ºStep – Mapping the Setup process: With the help of the VSM tool, the setup tasks were identified, at the same time that waste activities and opportunities for improvement were recognised. In this step the duration of each task was also defined

2º Step - Classification and grouping of tasks in internal and external: With the grouping of tasks it was possible to reduce the number of trips.

3º Step - Transfer internal to external tasks: It was proposed, to buy stamps in duplicate and created a hydraulic press for testing the stamps. In this way, two task turned to be external. It was also included a third operator to carry out external tasks.

4º Step - Time reduction of internal and external tasks: The mechanic internal tasks have been reduced with the development of the Operational Parameters Sheet (FPO) and parts of the checklist, and the construction of a specific car. To reduce the time of the third operator external tasks, several measures were taken: For example, the layout of the washing room was changed, the washing process was normalized, two specific cars were constructed, which go directly in the kiln.

With the new normalized process, it is possible to reduce the setup time at least 35%.

6.3. Stage 2 - Minor stoppage reduction

To reduce the main minor stoppage incidences, caused by the bulk and leaflets, the seven KK steps have been applied.

a) Bulk

The three main problems detected were: Broken pills, fat pills and pills with excessive dust. For each of these problems improvement actions were implemented:

- **Broken pills:** For these problem, four improvement actions were suggested: to add to the hopper a support platform; to place fewer bags per barrel and to add air bags; to drop the rail which is outside the silo carpet; and to eliminate the activity of handling the pills with a shovel. However, just the last improvement action referred was implemented yet. Now the pills fall directly in a bag.
- **Fat pills:** Two action were taken: First, the maintenance appointment of the compression machines; secondly, the acquiring wider sypro tubes for the Product S5.
- **Excessive dust:** Two main action were done: Creation of holes in bulk routing guides and introduction of rips on the tubes that come out from the compression machines; and installation of a vacuum system in the blistering machine.

b) Leaflets

It was noticed the occurrence of two main problems: The leaflets can be poorly or not caught and poorly or not introduced in the packages.

Leaflets poortly or not caught: A more powerful vacuum pump and distributor for the respective line C was acquired.

Leaflets poorly or not introduced in the packages:

- To decrease the paper weight
- To introduce folds in the leaflet centre and tip
- Standardization of the tuning parameters
- To decrease the variety of the dimensions of the leaflets
- To control visually the belts

From the mentioned improvement actions, the vacuum pump and the distributer were acquired, the fold in the leaflet centre was introduced and the bets visual control frequently made. The decrease of paper weight has been successfully tested, however it is necessary to negotiate this change with the suppliers. The parameters for the standardization of the tuning parameters are being collected and are going to be introduced in the mechanics routine later.

6.4. Stage 3 - Machines speed increase

The main goal of this stage was to increase the line speed. For that, was implemented a Kamishibai audit. This audit challenges the mechanics to increase the speed of the line. At the same time it allows the supervisors to detect and resolve the problems and limitations that arise with higher speeds. In addition, it approximates the directors to gemba, allowing them to follow the lines operation and give support on solving problems, when needed. With application of the Kamishibai audit, it was possible to increase the lines speed to levels equal to or higher than those indicated by the suppliers of machines.

7. Results assessment and discussion

In this paper the data from the planning phase is compared with the last three weeks from the implementation phase. The planning phase corresponds to the period from October to November 2014. The implementation phase started in late February and ended in late July. The last three weeks are highlight in the following analysis, because it is in this period that the effects of the implemented improvements began to be evident. The results of each improvement stage are presented in Table 1.

Table 1: Results obtained with the improvement activities

	KL Tool	Line	Initial State	Atual State	Redution
Stage 1	SMED	Line A	4.2h	3.3h	-22%
		Line B	5.5h	3.9h	-29%
		Line C	4.8h	3.1h	-35%
Stage 2	KK - Bulk	Line A	5h	34h	+580%
		Line B	47h	5h	-90%
		Line C	20h	24h	+20%
	KK - Leaflets	Line A	10.4h	0h	-100%
		Line B	6h	1.3h	-78%
		Line C	32.9h	18.7h	-43%
Stage 3	Kamishibai	Line A	92%	98%	+6,5%
		Line B	86%	77%	-11%
		Line C	81%	90%	+11%

In Table 1 we can see that most of the results where positive.

Stage 1: The setup time reduced at least 22% in the three lines.

Stage 2: The improvement actions implemented to reduce the bulk incidences achieved good results. However the number of minor stoppages caused by bulk in the last three week increased in line A and line C. This value decreases in line A because the folding machine was replaced by another that uses leaflets already folded. Consequently the leaflets already bought had to be folded

manually which created minor stoppages, because some of them weren't well folded. In line C, the incidences increased because the bulk was repacked in the last weeks. The improvement actions related with leaflets achieved good results and were a success as seen in Table 1.

Stage 3: The problems related with high velocity values were mitigated and the lines speed increased at least 6,5%, exceptionally in the line B because in the last weeks were tested new products.

In Table 2 the main KPI of these work can be seen. Line A improved 9% is OEE. Line B decreased 10% his OEE value, due the new products that were tested as explained. The improvement action were a success in Line C increasing his OEE 64%. The global OEE increased 13%, however if the smallest value linked with the new products test is reject, is obtained an increase of 27%.

Table 2: OEE per line and global main results

Main Results	Initial State	Atual State	Increase
OEE Line A	35%	39%	111%
OEE Line B	32%	28%	88%
OEE Line C	17%	27%	159%
Global OEE	28%	32%	114%

Empresa X had almost no Lean culture, and therefore there was some resistance throughout this work. As mentioned in the Literature Review, the role of leaders is essential to implement this culture. For these leaders the problems occurred only once, so they didn't need to take any action to prevent its recurrence. It was necessary to transmit and teach the leader how to be lean leaders. The support of the board, who went several times to Gemba, setting an example, was fundamental for that purpose. If there had been less resistance and more availability from the leaders, it would have been possible to achieve benefits quicker.

There is still variability in the Global OEE, because the lines experience unexpected problems, such as those mentioned. A longer period is necessary to take concrete conclusions of the advantages of this implementation, since these processes take some time until they are rooted and running at its maximum potential.

8. Conclusions

The case study in this paper was held at Empresa X, which aims to increase the efficiency of three packaging lines of drug.

Following the structure proposed by Melton, to apply Lean Thinking first were collected and analyzed the data required. Then improvements activities were drawn together with the team. The four activities of improvements that appeared aimed to reduce losses and identified waste, and are: 0) basic stability, 1) reduce setup time, 2) reduce minor stoppages related to bulk and leaflets, and 3) increase lines speed.

Later the proposed improvements were applied. With the implementation of Kaizen Daily (KD) and construction of the Mission Control Room (MCR) was possible to create a daily culture of continuous improvement at Empresa X.

From the results analysis it was concluded that the Global OEE increased 27% in the last weeks from the implementation phase, increasing the OEE from line C, the line with the lower OEE, ten percentage points. With stage 1 it was possible to reduce at least by 22% the initial setup time. In stage 2, it was possible to reduce 90%, with the support of Kobetsu Kaizen

(KK), the number of minor stoppages caused by bulk in line B. Also the problems related with leaflets were minimized, or even eliminated like in line A. Finally, in stage 3, with Kamishibai audits, the lines speed increased on average 6,5%.

To achieve the target, we need to conclude the implementation of all the suggested improvements and also to maintain discipline in the compliance of the established standards. Only then this work will be concluded and certainly better results will be achieved.

As a future work it is suggested that, after the stabilization of the new processes, new improvement activities should be implemented like: KK packages, lines layout change, logistics supply change and normalization of the third operator work.

9. References

- Ahire, C. P., & Relkar, A. S. (2012). Correlating Failure Mode Effect Analysis (FMEA) & Overall Equipment Effectiveness (OEE). *Procedia Engineering*, *38*, 3482–3486.
- Dart, R. C. (2011). Can Lean Thinking transform American health care? *Annals of Emergency Medicine*, *57*(3), 279–81.
- Dombrowski, U., & Mielke, T. (2013). Lean Leadership fundamental principles and their application. *Procedia CIRP*, *7*, 569–574.
- Fullerton, R. R., Kennedy, F. A., & Widener, S. K. (2014). Lean manufacturing and firm performance: The incremental contribution of lean management accounting practices. *Journal of Operations Management*.
- Gupta, A. K., & Garg, R. K. (2012). OEE Improvement by TPM Implementation : A Case Study, *1*(1), 115–124.
- Holweg, M. (2007). The genealogy of lean production. *Journal of Operations Management*, *25*(2), 420–437.
- Melton, T. (2005). The Benefits of Lean Manufacturing. *Chemical Engineering Research and Design*, *83*(6), 662–673.
- Mo, J. P. T. (2009). The role of lean in the application of information technology to manufacturing. *Computers in Industry*, *60*(4), 266–276.
- Radnor, Z. J., Holweg, M., & Waring, J. (2012). Lean in healthcare: The unfilled promise? *Social Science and Medicine*, *74*, 364–371.
- Sütőová, A. (2012). Kobetsu Kaizen – its value and application, 108–110.
- Uitdehaag, J. C. M. (2011). The seven types of drug discovery waste: toward a new lean for the drug industry. *Drug Discovery Today*, *16*(9-10), 369–71.
- Verrier, B., Rose, B., Caillaud, E., & Remita, H. (2013). Combining organizational performance with sustainable development issues: the Lean and Green project benchmarking repository. *Journal of Cleaner Production*.